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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/573,564	03/27/2006	Tetsuya Kuhara	TOYA108.014APC	7010

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KNOBBE MARTENS OLSON & BEAR LLP		
2040 MAIN STREET		
FOURTEENTH FLOOR		
IRVINE, CA 92614		

EXAMINER	
LANDSMAN, ROBERT S	

ART UNIT	PAPER NUMBER
1647	

NOTIFICATION DATE	DELIVERY MODE
08/10/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jcartee@kmob.com
eOAPilot@kmob.com

Office Action Summary

Application No.

10/573,564

Applicant(s)

KUHARA ET AL.

Examiner

Robert Landsman, Ph.D.

Art Unit

1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 July 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) 5-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) is/are allowed.
- 6) ☒ Claim(s) 1-4 is/are rejected.
- 7) ☐ Claim(s) is/are objected to.
- 8) ☐ Claim(s) are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 6/15/07; 6/12/06; 3/27/06.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. .
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: .

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DETAILED ACTION

1. Formal Matters

- A. Claims 1-21 are pending. Claims 1-4 have been elected. Therefore, claims 5-21 are withdrawn and claims 1-4 are the subject of this Office Action.

2. Answer to Traversal

- A. Applicants elected Group I, claims 1-4, with traverse. However, since no traversal has been provided, the election will be treated as an election without traverse. Therefore, this Restriction is deemed proper and is, therefore, made FINAL.

3. Claim Objections

- A. Claims 2-3 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claims 2 and 3 recite the same drug composition as claim 1. The only added steps are how much to administer and how to administer. However, the claims are not drawn to methods, but to the drug, itself. Therefore, regardless of how the drug is administered, or in what amount, the composition claims are drawn to the same drug.

4. Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

- A. Claims 1-4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 recites that the compounds are separately packaged in the drug. However, it is unclear how a drug can comprise of two separately packaged compounds. As used in the art, the term drug implies, e.g., a pill, tablet, capsule, etc. it is unclear how Applicants are defining the term "drug" to where it can comprise different packages.

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5. Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

A. Claims 1, 3 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wang et al. (on the 1449 filed March 27, 2006) as applied to claims 1-4 above, and further in view of Schmidt et al. (J. Immunology 172:138-143, 2004). The claims recite a drug for the proliferation of NK cells wherein said drug comprises lactoferrin and a TLR. Wang et al. teach that lactoferrin can increase NK number (Abstract). However, Wang does not teach that TLRs can increase NK proliferation. However, Schmidt do teach that Toll-like receptor ligands, including polyIC, can activate NK cells (Abstract). Therefore, it would have to one of ordinary skill in the art at the time of the present invention to have combined the teachings of Wang et al. and Schmidt et al. not necessarily for the purpose of proliferating NK cells, since the use of TLRs for that purpose is not taught, nor implied, by the prior art. The motivation to combine these references would have come from the desire of the artisan to combine two drugs, both having the ability to stimulating NK cell activity, which was clearly known in the prior art, for the purpose of increasing NK cell activity to treat such conditions as cancer, or other diseases requiring increased NK activity. The motivation for claim 3 comes from the fact that administering polyIC orally would not be the most effective route to avoid undesired biotransformation of the drug. The Examiner cannot make a prima facie case for claim 2 since the exact dose, or dosing schedule for this purpose is not obvious given the fact that TLRs could not be shown to possess the claimed activity.

6. Conclusion

A. No claim is allowable.

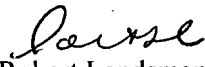
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Advisory information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Landsman whose telephone number is (571) 272-0888. The examiner can normally be reached on M-Th 10 AM – 7 PM (eastern).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol at 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Robert Landsman, Ph.D.
Primary Examiner
Art Unit 1647